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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	114474-14-FESI00002US	5214
38492	7590	10/02/2006	EXAMINER	
WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099			GILLAN, RYAN P	
			ART UNIT	PAPER NUMBER
			3746	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,762

Applicant(s)

YANASE ET AL.

Examiner

Ryan P. Gillan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-9,11 and 13-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-9,11 and 13-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/28/2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The amendment filed 5/04/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated (see claims 1, 18, 32 and 41).
2. Applicant has stated in the Specification that the "peripheral side surface that is in contact with the inner surface of the syringe barrel and/or a bottom surface that is in contact with liquid is laminated" and never prohibits the lamination of the bottom portion or excludes all other lamination except the peripheral side surface that is in contact with the inner surface of the syringe barrel. Additionally the only drawing depicting this lamination is described to have both the bottom surface and the peripheral side surface that is in contact with the inner surface of the syringe barrel laminated.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1, 18, 32 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added material which is not supported by the original disclosure is as follows: only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated (see claims 1, 18, 32 and 41).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 6-10, 12, 16-18, 23 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and Sudo et al. (U.S. 5,009,646).

With respect to claims 1, and 3, Trull et al., in Figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 6 attached to the end of this office action) is provided, and a periphery of a bottom surface

of the gasket that is not in contact with the liquid is formed into a tapered slant (also labeled by the examiner on Figure 6).

The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin. Sudo et al., discloses that a syringe gasket (2) is commonly coated (3) with a thermoplastic resin such as polyethylene (col. 2 lines 10-24). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket (col. 1 lines 48-55). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al., in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

With respect to claim 3, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 6-8, 19, 21, 22 and 24-28 there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claims 3, 6-8, 19, 21, 22, and 24-28, where the general conditions of a claim are disclosed in the prior

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art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claims 9 and 10, a second tapered (see examiner's marked up Figure 6) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel (60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

7. Claims 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Sudo et al., as applied to claims 1 and 9, and in further view of Akaike et al. (U.S. 5,061,247).

Trull et al., as modified by Sudo et al., set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al., as modified by Sudo et al. device differs from the claimed invention in that there is no disclosure of to the gasket being made integrally of a material with JIS hardness of 55 to 60. Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is suitable for gaskets applied to syringe devices. This general range covers the applicants claimed

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range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Sudo et al., gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. Other than the range being preferred for presumably general optimum device function, the applicant has provided no criticality or unexpected or non-obvious advantage over choosing one this particular range. The coating taught by the prior art is integral in that the coating and the plunger coated form an integral plunger assembly.

8. Claims 11 and 13, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Sudo et al., as applied to claims 1 and 9, and in further view of Higashikawa (U.S. 5,830,193).

Trull et al., as modified by Sudo et al., set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al., as modified by Sudo et al., device differs from the claimed invention in that there is no disclosure of the syringe including a luer lock. Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that luer lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) – see column 7 line 49. Therefore it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Sudo et al., device by incorporating the luer locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

9. Claims 33-37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. in view of Smith et al. (5,597,530). The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with silicon. Smith et al., discloses that a syringe gasket (2) is coated (3) silicon (col. 2 lines 10-24). Such material is effective in that it eliminates the need for a lubricant and serves as a protective coating for the gasket (col. 1 lines 48-55). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material laminated with silicon, as taught by Smith et al., in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

With respect to claim 34, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 34-37 there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With

respect to the specified gasket dimensions in claims 34-38, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claim 40, a second tapered (see examiner's marked up Figure 6) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel (60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Smith et al., in further view of Akaike et al. (U.S. 5,061,247).

Trull et al., as modified by Smith et al., set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al., as modified by Smith et al. device differs from the claimed invention in that there is no disclosure of the gasket being made integrally of a material with JIS hardness of 55 to 60. Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is suitable for

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gaskets applied to syringe devices. This general range covers the applicants claimed range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Smith et al., gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. Other than the range being preferred for presumably general optimum device function, the applicant has provided no criticality or unexpected or non-obvious advantage over choosing one this particular range. The coating taught by the prior art is integral in that the coating and the plunger coated form an integral plunger assembly.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Smith et al., and in further view of Higashikawa (U.S. 5,830,193).

Trull et al., as modified by Smith et al., set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al., as modified by Smith et al., device differs from the claimed invention in that there is no disclosure of the syringe including a luer lock. Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that luer lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) – see column 7 line 49. Therefore it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Smith et al., device by incorporating the luer locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Response to Arguments

12. Applicant's arguments filed 6/30/06 have been fully considered but they are not persuasive. The applicant argues that the prior art fails to teach selectively laminating in the manner described in claim 1, however claim 1 recites a "syringe *comprising*" and therefore does not exclude additional features. The prior art recites only the peripheral side surface that contacts the inner surface of the syringe is laminated and additionally laminates the bottom portion and therefore, satisfies the limitations of the claim.

13. The applicant's argument with regard to the motivation to combine the prior art references of Trull et al. and Ito is moot in view of the new grounds of rejection.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan P. Gillan whose telephone number is 571-272-8381. The examiner can normally be reached on 8:30 am - 5:00 pm; Monday - Friday.

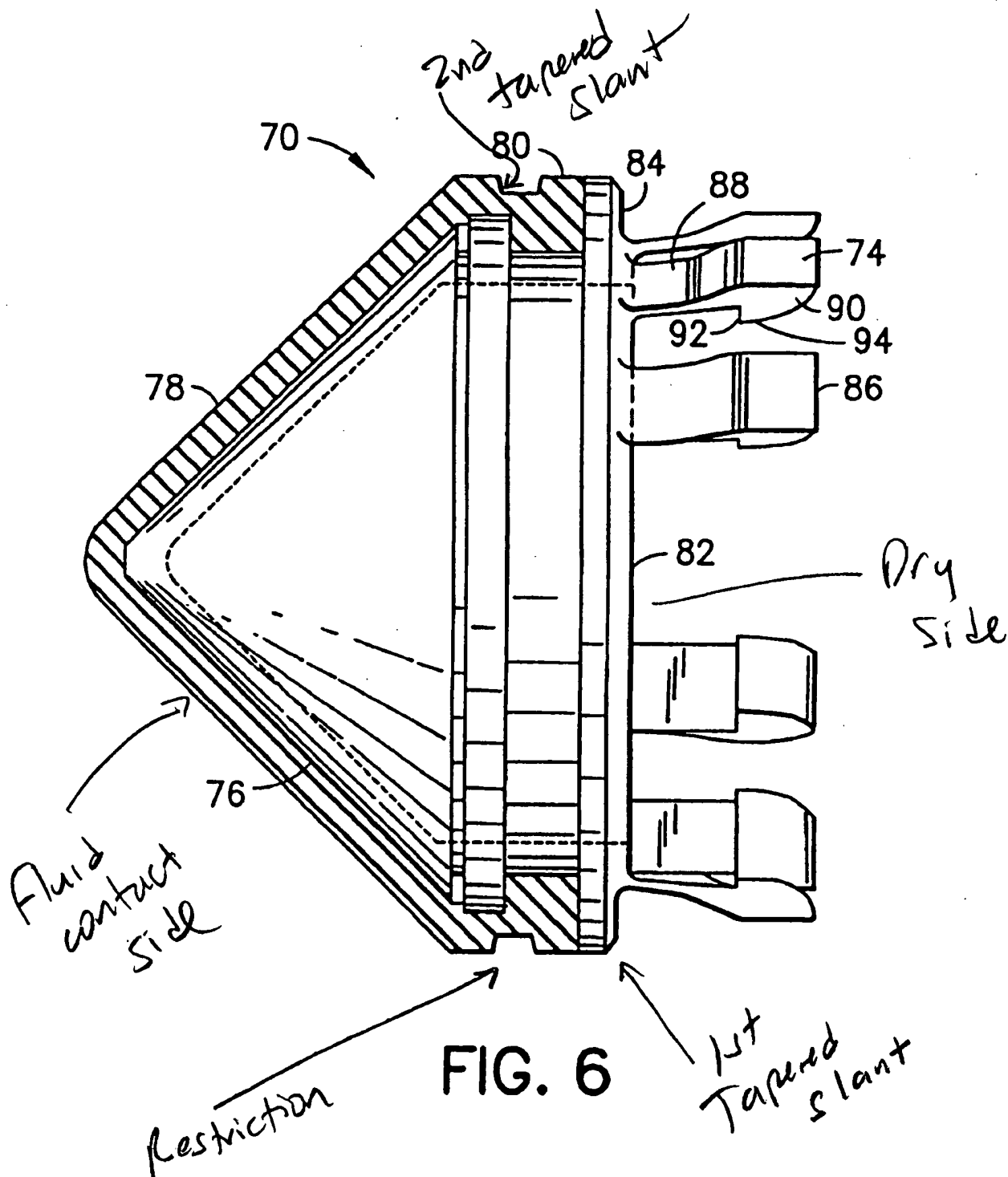
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on 571-272-4444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ANTHONY D. STASHICK
PRIMARY EXAMINER



Examiner's marked Figure
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